REMARKS UNDER 37 CFR § 1.111

Formal Matters

Claims 2, 11, 17, 19, 43 and 71-90 are pending after entry of the amendments set forth herein.

Claims 2, 11, 17, 19, 43 and 71-89 were examined. Claims 2, 11, 17, 19, 43 and 71-89 were rejected.

Applicants respectfully request reconsideration of the application in view of the amendments and remarks made herein.

No new matter has been added.

The Office Action

Claims Rejected Under 35 U.S.C. Section 102(b) (Kaster et al.)

In the Official Action of March 17, 2008, claims 2, 11, 17, 19, 75-77 and 83-85 were rejected under 35 U.S.C. Section 102(b) as being anticipated by Kaster et al., U.S. Patent No. 5,234,447. The Examiner asserted that she interpreted the definition of "sinuous" to mean "many turns" and asserted that the connecting unit 46 of Kaster et al. has "many turns" and is formed of a deformable material, which the Examiner interpreted to be "malleable sections".

Applicants respectfully traverse and submit that the connecting unit 46 of Kaster et al. is a ring structure having an annular shape, see column 6, lines 7-8. As such, the structure of connecting unit 46 has only one constant radius turn over 360 degrees. It is respectfully submitted that a ring structure is not sinuous, and that the Examiner has misinterpreted the Kaster et al. reference. Further, Applicants have amended claim 1 above to clarify that the malleable sections each have an apex , wherein the apex of each malleable section extends further peripherally outward than the other portions of that malleable section. Support for this amendment can be found, for example, at pages 30-32 of the specification and throughout the specification. It is respectfully submitted that the ring of Kaster et al. clearly does not have malleable sections as claimed, since all portions of the ring of Kaster et al. extend peripherally (radially) by the same distance.

As to claims 11 and 17, it is respectfully submitted that the staple apparatus of Kaster et al. is not configured to orient the edge surface of first and second vessels to align the edge surfaces to join, as claimed. Rather, the edge of wall 53 accommodates the exterior wall of the vessel 51, see Figs. 17-19 and col. 6, lines 57-65. Further in regard to claim 11, Kaster et al. fails to disclose, and the Examiner has not even asserted that Kaster et al. joins vessels in side-to-side contact. It is respectfully submitted that Kaster et al. is not configured for, and cannot join vessels in side-to-side contact.

As to claim 19, the Examiner asserted that Kaster et al. discloses a tool having a head configured to be inserted into one of the vessels to attach means 43,44 for attaching to the vessel. Referring to Figs. 1-7 of Kaster et al., the Examiner asserted that the head is located at a distal end portion of said tool, However, the Examiner did not identify by reference numeral, or specific description, what is interpreted to be the "head" of Kaster et al. The Examiner asserted that the tool has a bypass channel 18 defined through and an anvil 28 at the head.

Applicants respectfully traverse the Examiner's interpretation. It is respectfully submitted that a plurality of longitudinally oriented slots 23 are formed in the forward end 24 of the core unit 14, see column 4, lines 42-45. The slots act to form a plurality of fingers 26. Each finger has a groove 27 formed therein and disposed substantially parallel to the slots and the axis of the core unit.

The hole 18 extending through the sleeve extends longitudinally therethrough and cannot be properly interpreted as a bypass channel extending transversely to the longitudinal axis.

Nor does Kaster et al. disclose a transversely extending head that has a bypass channel defined therethrough. Rather, the forward end of the sleeve 13 of Kaster et al. has a cavity 21 that serves as an anvil. Cavity 21 is concave shaped and formed annularly about hole 18, see column 4, lines 31-34. Clearly an annularly formed, concave-shaped cavity cannot be correctly interpreted to be a head that extends transversely to a longitudinal axis of a head, wherein the head has a bypass channel defined therethrough that extends transversely to the longitudinal axis, as recited in claim 19.

Claim 76 recites that the anvil is larger than the incision in the vessel into which it is inserted and is configured to be button holed into the vessel. It is respectfully submitted that the anvil 21 of Kaster et al. is configured to remain outside of the vessel 53, see Figs. 18-19.

With regard to claim 85, it is respectfully submitted that Kaster et al. lacks docking extensions as claimed.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 2, 11, 17, 19, 75-77 and 83-85 under 35 U.S.C. Section 102(b) as being anticipated by Kaster et al., U.S. Patent No. 5,234,447, as being clearly inappropriate.

Claims Rejected Under 35 U.S.C. Section 102(b) (Sakura, Jr.)

Claim 43 was rejected under 35 U.S.C. Section 102(b) as being anticipated by Sakura, Jr., U.S. Patent No. 4,214,587. The Examiner asserted that Sakura, Jr. teaches a method of performing an anastomosis comprising defining a first and second incision (Figs. 6-9), fastening the mounting structure to the first structure (Fig. 6) and fastening the mounting structure to the second vessel (Fig. 7), shaping the mounting structure to define a desired flow (Figs. 7 and 8).

Applicants respectfully traverse. The device of Sakura, Jr. is a radially resilient spring, see the abstract. The Examiner has not replied to this point, as to how Sakura, Jr. can correctly be interpreted to perform shaping, by bending the mounting structure to define a desired flow area, when Sakura, Jr. uses a resilient spring.

Further, it is respectfully submitted that Sakura, Jr. clearly fails to disclose or suggest "fastening a mounting structure in surrounding relationship to the incision" in the first vessel or in the second vessel, as Figs. 6 and 7 of Sakura, Jr. clearly show that the device is inserted inside of at least one of the vessels. To clarify this distinction, claim 43 has been amended to recite that the mounting structure surrounds the incision in the first vessel and the mounting structure surrounds the incision in the second vessel. This is clearly not the case with the method of Sakura, Jr.

Further, it is respectfully submitted that Sakura, Jr. fails to disclose or suggest that the inside edges of the incisions in the first and second vessels are brought into healing contact. Figs. 18A and 18B of the present invention show an example of contacting the edges together. It is respectfully submitted that Sakura, Jr. clearly fails to disclose this feature, as the edges of the vessels are clearly shown in Fig. 9 in a side-by-side orientation where they are not contacting each other.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of 43 under 35 U.S.C. Section 102(b) as being anticipated by Sakura, Jr., U.S. Patent No. 4,214,587, as being clearly inappropriate.

Claims Rejected Under 35 U.S.C. Section 103(a) (Kaster et al. in view of Elefteriades)

Claims 71, 87 and 89 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Kaster et al., U.S. Patent No. 5,234,447 in view of Elefteriades, U.S. Patent No. 4,787,391. The Examiner asserted that Kaster et al. discloses the claimed invention except for a hemostatic medium coating a woven synthetic cuff. Applicants respectfully traverse, for at least the reasons provided above with regard to claim 2.

The Examiner asserted that Elefteriades discloses an anastomotic device that uses an absorbable hemostatic sheet (Abstract, line 4 referred to), and that it would have been obvious to include a hemostatic medium coating on the anastomotic apparatus [of Kaster et al.] to allow the incision in the tissue to heal faster which could help to prevent infection.

Applicants respectfully traverse. As noted previously, Elefteriades does not teach a hemostatic medium positioned to contact the outsides surfaces of the first and second vessels as the edge surfaces of the incisions are brought into contact. Rather, Figs. 2-4 appear to show the outside wall of vessel 26 contain the edge of aorta 30. Since neither Kaster et al. nor Elefteriades teaches or suggests bringing the edge surfaces of the two vessels together, it is submitted that Elefteriades cannot teach a hemostatic medium positioned to contact the outside surfaces of the first and second vessels as the edge surfaces of the incisions are brought into contact, contrary to the Examiner's assertions.

The same comments apply to claim 87. Further, claim 87 has been amended to clarify that the edges of the incisions are defined by the tissue between the inner and outer wall of the first and second vessel, respectively. An example of this is shown by 26 and 26' in Fig. 19. brought into abutting contact. Claim 89 has been amended to recite malleable sections each having an apex that extends further peripherally outward than the remainder of that respective malleable section, which Kaster et al. fails to disclose, as noted above with regard to Fig. 2, which Elefteriades also fails to disclose or suggest.

Accordingly, in view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 71, 87 and 89 under 35 U.S.C. Section 103(a) as being unpatentable over Kaster et al., U.S. Patent No. 5,234,447 in view of Elefteriades, U.S. Patent No. 4,787,391, as being inappropriate.

Claims Rejected Under 35 U.S.C. Section 103(a) (Sakura, Jr. in view of Elefteriades)

Claims 71, 87 and 89 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Sakura, Jr., U.S. Patent No. 4,214,587 in view of Elefteriades, U.S. Patent No. 4,787,391.

It is respectfully submitted that the rejection of claim 71 under this ground of rejection is improper, since claim 2, from which claim 71 depends was not rejected over Sakura, Jr. or the combination of Sakura, Jr. and Elefteriades.

The Examiner asserted that Sakura, Jr. discloses the claimed invention except for a hemostatic medium coating a woven synthetic cuff. Applicants respectfully traverse. Claim 2 recites that the stiffening framework has a plurality of malleable sections. Sakura, Jr. discloses a resilient spring, see column 3, lines 53-55. The Examiner did not respond to this argument, which was also made in the previous amendment. If the Examiner intends to maintain this ground of rejection, the Examiner is respectfully requested to explain how a resilient spring can be interpreted to define malleable sections.

Further, Sakura, Jr. does not hold the inside edges of the vessels in contact as already noted above. T

The Examiner asserted that Elefteriades discloses an anastomotic device that uses an absorbable hemostatic sheet (Abstract, line 4 referred to), and that it would have been obvious to include a hemostatic medium coating on the anastomotic apparatus [of Sakura, Jr.] to allow the incision in the tissue to heal faster which could help to prevent infection.

Applicants respectfully traverse. It is respectfully submitted that Elefteriades does not teach a hemostatic medium positioned to contact the outsides surfaces of the first and second vessels as the edge surfaces of the incisions are brought into contact. Elefteriades discloses a marking device used to locate the site where an anastomosis has been performed. Thus, the device of Elefteriades is positioned around the site of anastomosis after performing the anastomosis, see column 4, lines 27-38. Accordingly, even if it would have been obvious to combine the references as suggested by the Examiner, which Applicants do not necessarily agree that it would have been obvious, the resultant combination would still not meet the limitations of claim 71, since the marker of Elefteriades would be placed after performing the anastomosis, and would not contact the outside surfaces of first and second vessels as the edges surfaces of the incision are brought into contact.

The same comments apply to claim 87. Further, claim 87 has been amended to clarify that the edges of the incisions are defined by the tissue between the inner and outer walls of the vessel along the incision, as noted above.

Accordingly, in view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 71, 87 and 89 under 35 U.S.C. Section 103(a) as being unpatentable over Sakura, Jr., U.S. Patent No. 4,214,587 in view of Elefteriades, U.S. Patent No. 4,787,391, as being inappropriate.

Claims Rejected Under 35 U.S.C. Section 103(a) (Kaster et al. in view of Elefteriades and Chen)

Claims 72-73 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Kaster et al., U.S. Patent No. 5,234,447 in view of Elefteriades, U.S. Patent No. 4,787,391, as applied to claim 71 above, and further in view of Chen, U.S. Patent No. 5,336,233. The Examiner asserted that Kaster et al. and Elefteriades disclose an anastomotic apparatus that can be shaped into an oval.

Applicants respectfully traverse this assertion. In the previous amendment filed February 13, 2007, Applicants respectfully submitted that there is no disclosure within Elefteriades that suggests that the donut shaped sheet can be shaped into an oval-shape, and that the Examiner's statement is a conclusion unsupported by the disclosure. In the Final Office Action dated June 19, 2007, the Examiner failed to address this traversal. In the current Office Action dated March 17, 2008, the Examiner again did not address this traversal. MPEP 707.07(f) states: "Where the applicant traverses any rejection, the examiner should, if he or she repeats the rejection, take note of the applicant's argument and answer the substance of it." The Examiner is therefore respectfully requested to indicate where Elefteriades discloses, teaches or suggests that the donut shaped sheet of Elefteriades can be shaped into an oval shape, or withdraw this ground of rejection as being unsupported by the references.

Further, even if the device of Kaster et al. were to be shaped into an oval shape (although there is no suggestion to do so in any of the applied references), the sheet of Elefteriades, if combinable at all with Kaster et al., would be overlaid around the site of the anastomosis after performance thereof, and would be circular shaped, as disclosed.

The Examiner further asserted that it would have been obvious to use a woven synthetic material, as taught by Chen, as it has well-known properties relied upon in successful use in many medical applications. Applicants respectfully traverse. It is respectfully submitted that the annuli pair provided by Chen are for an entirely different function that that disclosed by Elefteriades. For example, the annuli pair of Chen are structural members used to perform a clamping function, whereas the device of Elefteriades is a sheet meant to adhere to an external surface where an anastomosis has already been performed. Accordingly, since these are two completely different devices, it is respectfully submitted that Chen would not have provided an appropriate teaching for materials that would be obvious to use in the sheet of Elefteriades.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 72-73 under 35 U.S.C. Section 103(a) as being unpatentable over Kaster et al., U.S. Patent No. 5,234,447 in view of Elefteriades, U.S. Patent No. 4,787,391, as applied to claim 71 above, and further in view of Chen, U.S. Patent No. 5,336,233, as being clearly inappropriate.

Claims Rejected Under 35 U.S.C. Section 103(a) (Kaster et al. in view of Chen)

Claims 78-82, 86 and 88 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Kaster et al., U.S. Patent No. 5,234,447, as applied to claims 2 and 77 above, and further in view of Chen, U.S. Patent No. 5,336,233. The Examiner asserted that Kaster et al. discloses an anastomotic device with a sinuous stiffening framework with a plurality of malleable sections, but does not have a male and a female member that form a friction fit using rivets. Applicants respectfully traverse. It is respectfully submitted that Kaster et al. does not disclose a sinuous stiffening framework, nor does Kaster et al. provide a framework with a plurality of malleable sections having apexes as recited in claim 2, for the reasons provided above with regard to the rejection of claim 2 under 35 U.S.C. Section 102(b) over Kaster et al.

The Examiner asserted that Chen teaches an anastomotic device that has a male and female member (Fig. 2) that form a friction fit using rivets, column 3, line 46. The Examiner asserted that it would have been obvious to use mating members for Kaster's apparatus to insure that the tissue formed at the anastomosis remains together.

In the amendment filed February 13, 2007, Applicants respectfully submitted that neither Kaster et al. nor Chen discloses or suggests bridging members connecting first and second portions that can be manipulated to draw the first and second portions together, as recited in claim 78 and 88, and further described in claim 86. In the current Final Office Action dated June 19, 2007, the Examiner failed to address this traversal, but simply repeated the comments made in the previous Office Action. In the current Office Action, the Examiner has again failed to address the substance of the traversal. MPEP 707.07(f) states: "Where the applicant traverses any rejection, the examiner should, if he or she repeats the rejection, take note of the applicant's argument and answer the substance of it." The Examiner identified that Chen is interpreted to use rivets, which apparently are considered to meet the recitation of male an female connectors that form a friction fit with one another.

However, claim 78 recites bridging members interconnecting firs and second portions of a single cuff. It is respectfully submitted that Chen clearly fails to disclose such bridging members. Nor do Kaster et al. or Elefteriades disclose the claimed bridging members that can be manipulated to draw first and second portions of a single cuff together to draw the edge surfaces of the incisions into contact.

The Examiner asserted that it would have been obvious "to have mating members for the anastomotic apparatus...". Presumably, the Examiner is referring to the apparatus of the base reference of Kaster et al. However, Kaster et al. disclose a single, unitary staple and so there would have been no need for the rivets of Chen, since an integral staple does not need to have its parts held together. It also would not have been obvious to form Kaster et al. into two parts merely for the reason of providing rivets as taught by Chen in order to keep the two parts together.

The Examiner's indication that "Using a male and female mating device also decreases the amount of tissue damage, because the two parts are connecting to each other through the pins instead of through additional sutures through the tissue" is unsupported by the references and speculative. The Examiner is respectfully requested to identify where this conclusion is supported in one or more of the references, or to supply another reference that supports the Examiner's allegation as fact.

Accordingly, in view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 78-82, 86 and 88 under 35 U.S.C. Section 103(a) as being unpatentable over Kaster et al., U.S. Patent No. 5,234,447, as applied to claims 2 and 77 above, and further in view of Chen, U.S. Patent No. 5,336,233, as being clearly inappropriate.

New Claim 90

New claim 90 has been submitted above to depend from claim 2. Support for this claim can be found, for example, at pages 30-32 of the specification and throughout the specification. The Examiner is respectfully requested to indicate the allowance of claim 90 in the next Official Action.

Conclusion

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-2653, order number GUID-101CON4.

Respectfully submitted,

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Date: 6/19/08

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